

**REMARKS/ARGUMENTS**

Claims 1-59 were pending. The claims have been amended, canceled, and new claims added as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

All claims were rejected as being anticipated by U.S. Patent No. 6,740,082 to Shadduck or being obvious over the combination of Shadduck in view of various secondary references.

Applicants note that the Shadduck '082 describes a device for treating the LES which relies on delivering radiofrequency energy, not ultrasonic energy. While the Examiner correctly points out that Shadduck does mention ultrasonic energy as an alternative to radiofrequency energy (e.g. at Col. 10, line 33), Applicants note that the device described by Shadduck, as a whole, is specifically intended for engaging a plurality of radiofrequency electrodes 45 directly against tissue. While the device does have a balloon 50, the balloon is disposed on the side of the catheter opposite to that of the electrodes, and the balloon is not intended to surround the electrodes or facilitate delivering energy from the electrodes, as will be discussed below with respect to the present invention. Indeed, the presence of a balloon around the radiofrequency electrodes would prevent them from delivering energy into the tissue of the LES.

For these reasons, Applicants believe that independent claims 1 and 44, the only pending independent claims, distinguished Shadduck even prior to amendment. In particular, claim 1 set forth the positioning of a cylindrical vibrational transducer. While Shadduck does mention ultrasound energy in passing, nowhere does Shadduck teach or suggest using a cylindrical vibrational transducer. Nor does Shadduck teach energizing "selected longitudinal divisions of the vibrational transducer to produce" the acoustic energy which is delivered to the tissue for remodeling. Shadduck does teach parallel electrodes, but they are in no way equivalent to longitudinal divisions of a vibrational transducer.

Nonetheless, in order to expedite prosecution of the present application, Applicants have amended both independent claims 1 and 44 to further distinguish the teachings

of Shadduck. In particular, independent claim 1 has been amended to recite that the cylindrical vibrational transducer is positioned “within a balloon” and that the balloon is inflated “with an acoustically transmissive medium” so that it “engages the balloon against a luminal wall.” Thus, when the selected longitudinal divisions of the vibrational transducer are energized, the acoustic energy is “transmitted through the acoustically transmissive fluid to the luminal tissue.”

Independent apparatus claim 44 has been amended similarly to recite that the apparatus includes “means for inflating the balloon with an acoustically transmissive medium” and that the cylindrical vibrational transducer is disposed “within the balloon.”

Shadduck nowhere teaches such a structure, and indeed such a structure would be incompatible with the use of radiofrequency electrodes, which is the only structure which is described in any detail.

The limitations now introduced into independent claim 1 were generally found in dependent claims 15 and 16, which now have been canceled. Dependent claim 15 set forth that the balloon was inflated to engage the luminal wall and locate the transducer at a predetermined position relative to the target site. Dependent claim 16 further recited that the balloon was inflated with acoustically transmissive material which positions the transducer therein and enhances transmission of the acoustic energy to the tissue. Dependent claim 15 was rejected as being anticipated by Shadduck, but dependent claim 16 was rejected over Shadduck in view of U.S. Patent No. 5,720,287 to Chapelon. The Examiner relies on Chapelon as disclosing “a therapy probe for ultrasound therapy and further teaches a transducer probe surrounded by a flexible membrane . . . which is filled with an acoustic-coupling liquid . . .” While this characterization is not incorrect, Applicants wish to point out that Chapelon specifically describes a generally rigid probe having a window which allows the transmission of ultrasonic energy. The energy is focused ultrasound, and the window is in no way equivalent to the balloon of the present invention which is inflated within a body lumen in order to position a cylindrical transducer therein. The window of Chapelon is meant to operate with the focused disc-shaped transducer and would be incompatible with the cylindrical transducer of the present invention which directs energy over the entire circumference of the balloon. Even if one skilled in the art were to combine the teachings of Shadduck with those of Chapelon, the result would more likely

be providing the RF electrodes of Shadduck on a rigid shaft for positioning, or possibly providing a balloon on the exterior of the rigid shaft of Chapelon. There would be no reason or benefit to substituting the balloon of Shadduck for the rigid probe body of Chapelon which is needed for the high energy focused ultrasound transmitter disclosed therein.

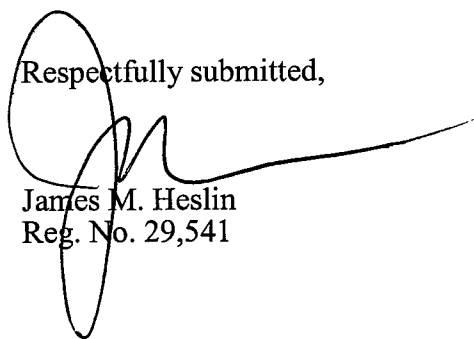
Applicants note that new dependent claims 63-65 have been added which are directed at a particularly preferred feature of the present invention. The feature is use of a material which selectively absorbs acoustic energy to enhance heating at the surface of the lumen. The feature is described, for example, in paragraphs 16, 131, and 161 of the specification.

### CONCLUSION

In view of the above amendments and remarks, Applicants believe that all claims are now in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,



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